

EXHIBIT I

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

04 CR 10367 DPW

UNITED STATES OF AMERICA,

v.

ADAM STUPAK,

Defendant.

) Criminal Number _____
)
)
)
) VIOLATION:
)
) 42 U.S.C. § 1320a-7b(b)(2)(A)
) Offering To Pay Illegal Remunerations
) 18 U.S.C. § 2 - Aiding and Abetting
)
)

INFORMATION

The United States Attorney charges:

PRELIMINARY ALLEGATIONS

At all times material hereto, unless otherwise alleged:

The Defendant

1. The defendant **ADAM STUPAK** (hereinafter referred to as **STUPAK**) was employed as a clinical consultant and Regional Director for Serono Laboratories, Inc., a subsidiary of Ares-Serono, S.A ("SERONO"). **STUPAK** worked for SERONO from August 1996 until November 15, 2000.
2. From August 1996 until July 1997, **STUPAK** was a clinical consultant (the title SERONO used for its sales representatives) in Brooklyn and the Bronx in New York. In August of 1997 he was promoted to Regional Director for sales in the "Tri-State Region," which included New York, New Jersey and Connecticut. In January 1998, SERONO realigned its sales regions and his territory was limited to New York and called the "Empire Thunderbolts."

Serono Laboratories Inc. and Serostim

3. SERONO is an international pharmaceutical and bio-technology company with corporate headquarters in Geneva, Switzerland. SERONO headquarters in the United States was at all relevant times located in Massachusetts.
4. At all times relevant, **STUPAK** was responsible for sales and marketing of the drug Serostim, which is the propriety name or trademark of the generic drug, “somatropin.” Somatropin is recombinant human growth hormone, consisting generally of growth hormone taken from an animal and modified, using DNA technology, by the addition of the human growth hormone gene. SERONO received accelerated approval from the U.S. Food and Drug Administration (“FDA”) in 1996 for Serostim to treat AIDS wasting, also known as cachexia, a condition involving profound involuntary weight loss in AIDS patients. At the time the FDA approved Serostim, AIDS wasting was an AIDS defining condition that constituted the leading cause of death among AIDS patients.
5. Serostim came on the market concurrently with the advent of protease inhibitor drugs. These drugs, often referred to as Highly Active Anti-Retroviral Therapy, or HAART, dramatically curtailed, in the United States, the proliferation of the AIDS virus itself, particularly when used in combination with one another (commonly referred to as “AIDS cocktails”). Given the decreased viral loads in HIV patients taking these drugs, the incidence and prevalence of the AIDS wasting syndrome began to markedly decline among AIDS patients. Consequently, the demand for Serostim began to drop significantly immediately following launch of the drug in the Fall of 1996.

6. By February, 1999, the SERONO business unit responsible for selling Serostim, Metabolic & Immune Therapy ("M&IT"), was falling short of its sales forecasts. At the same time, top management of the M & IT business unit scheduled a National Sales Meeting in Massachusetts from March 15-19, 1999. These top managers of the M & IT business unit will be referred to in this Information as the "M & IT Management."
7. By this point, the sales force was lead by six Regional Directors, including the defendant **ADAM STUPAK**. Five other Regional Directors were responsible for the following sales territories: the Northeast region (Massachusetts, Maine, Connecticut, Vermont, New Jersey, parts of Pennsylvania and New York State); the Southeast region (Florida, Louisiana, Mississippi, Alabama and Texas); the Central region (Illinois, Wisconsin, Missouri, Arkansas, Oklahoma, Kentucky, Michigan, Minnesota, North Dakota, South Dakota, Nebraska, Iowa and Indiana); the Western region (California, Oregon, Washington, Arizona, and Colorado); and, the Mid-Atlantic region (Maryland, Delaware, Georgia, North Carolina, South Carolina, Ohio, West Virginia, and part of Pennsylvania).
8. On March 1, 1999, the six Regional Directors, including the defendant **ADAM STUPAK**, were summoned by the M & IT Management to a meeting in Boston, Massachusetts at the Boston Harbor Hotel. During the meeting, M & IT Management told the Regional Directors that they were falling far short of their sales forecasts and that they needed to "dig their way out" of this fiscal crisis. M & IT Management ordered the Regional Directors to target the top prescribing doctors

to induce them to write more prescriptions. In this regard, M & IT Management devised a plan called the "\$6m-6 Day Plan."

9. In this plan, each Regional Director, including the defendant **ADAM STUPAK**, was required to identify the highest prescribing physicians in his region. The plan required the Regional Directors, including the defendant **ADAM STUPAK**, to target those physicians with financial incentives in order to get the required number of prescriptions to achieve the sales goal of an increase in sales by \$6,000,000. In particular, it was a part of the plan to offer key high prescribing doctors (and a guest) an all expenses paid trip to the 3rd International Conference on Nutrition and HIV Infection to be held in Cannes, France on April 22-26, 1999, in return for writing, within one week, thirty prescriptions of Serostim. It was the expectation of the Regional Directors participating in this plan, including the defendant **ADAM STUPAK**, that each prescription of Serostim induced by the offer of an all expenses paid trip to Cannes, France, was for a twelve week course of treatment and had a value of approximately \$630,000 to Serono. In a written directive, a member of M & IT Management ordered each Regional Director to assign each clinical consultant a specific list of physicians that "they are to LIVE with until they get the required number" of prescriptions per targeted doctor.
10. The plan called for payment of the physician's expenses, in exchange for the scripts, in one of two ways: (1) SERONO offered the doctors a check in the amount of \$4,000 for their airfare to France; or (2) SERONO offered to make and pay for the flight arrangements for the doctors. It was also a part of the plan that SERONO would make and pay for the hotel accommodations, meals, and entertainment for

the doctors and their guests. The expected value of this trip per physician varied from a low of approximately \$5,000 to a high of approximately \$10,000, depending on the flight arrangements.

11. From March 3-11, 1999, M & IT Management required each Regional Director to report to SERONO headquarters daily the number of scripts that doctors wrote as a result of the visits made to doctors by the Regional Directors and their clinical consultants.
12. On or about March 2, 1999, **STUPAK** left Boston and returned to New York.
13. On or about March 2 or 3, 1999, **STUPAK**, together with a SERONO sales representative, visited the office of Dr. "O." Dr. O at that time practiced medicine in New York City and treated patients that were HIV positive and/or suffering from AIDS. During that meeting, **STUPAK** offered Dr. O the trip to the Cannes Conference in return for his writing at least 10 additional prescriptions of Serostim. Dr. O did not immediately accept or decline the offer of the Cannes trip.
14. On or about March 2 or 3, 1999, **STUPAK**, together with a SERONO sales representative, visited the office of Dr. "G." Dr. G at that time was engaged in the practice of medicine in New York City and treated patients that were HIV positive and/or suffering from AIDS. During that meeting, **STUPAK** offered Dr G the trip to the Cannes Conference in return for his writing at least 10 additional prescriptions of Serostim. While Dr. G initially agreed to accept the offer, he did not actually attend the conference.
15. On or about March 2 or 3, 1999, **STUPAK** also visited the office of Dr. "W." Dr. W at that time was engaged in the practice of medicine in New York City and

treated patients that were HIV positive and/or suffering from AIDS. During that meeting, **STUPAK** offered Dr W the trip to the Cannes Conference in return for his writing at least 10 additional prescriptions of Serostim. Dr. W agreed to accept the offer and wrote additional Serostim scripts during that week of March 3-11, 1999. A \$4,000 check for the airfare was issued by SERONO for Dr. W to attend the Cannes conference. The check was later voided when Dr. W did not go to Cannes.

16. During a presentation at SERONO's National Sales meeting held from March 15-19, 1999, the marketing department announced the names of ten physicians who were "US Invitees" to the Cannes Conference. During that announcement, the marketing department also falsely stated, in a slide presentation, that each of these physicians had "committed to conducting two regional speaking programs to summarize the meeting proceedings" when in fact, no such commitment had been requested or made.
17. Consistent with the "\$6m-6 days" plan and its target of thirty twelve-week prescriptions of the drug Serostim, the value of this business to SERONO totaled \$6,300,000, more or less.

The Medicaid Program

18. Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 et seq., established a program to enable the states to furnish medical assistance to certain categories of persons whose income and resources are insufficient to meet the costs of necessary medical services. Commonly called Medicaid, the program is administered by the states, but is funded jointly by the federal and state governments.

19. To participate in the Medicaid program, a state must develop a plan that is approved by the Secretary of Health and Human Services as meeting federal requirements. The state pays qualified providers for furnishing necessary services covered by the state plan to individuals who are eligible for medical assistance. The federal government contributes a proportion of the costs that each participating state incurs in purchasing items and services from qualified providers on behalf of eligible persons. The state bears the remainder of the costs. At all times relevant hereto, the State of New York had a Medicaid program that received federal funding and was a Federal Health Care Program.
20. The federal government contributes fifty percent of the costs of prescriptions for persons who are Medicaid beneficiaries, including but not limited to persons disabled due to HIV infection and AIDS under the New York State Medicaid program.
21. Medicaid paid for approximately 75% of all Serostim prescriptions nationwide. From 1996 through 1998, New York Medicaid reimbursed claims for Serostim totaling \$23,739,816.
22. Drs. O, G and W were providers who cared for Medicaid eligible patients suffering from AIDS. Dr. O, G and W prescribed at times Serostim to some of their patients who were Medicaid program beneficiaries, and New York Medicaid paid for Serostim prescriptions for certain of their patients.

COUNT ONE: [42 U.S.C. § 1320a-7b(b)(2)(A): Offering to Pay Illegal Remunerations]:

23. The allegations set forth in Paragraphs 1-22 are herein incorporated.

24. On or about March 1-3, 1999 in New York City, New York, the defendant

ADAM STUPAK,

did knowingly and willfully offer to pay remuneration, including a kickback and bribe, directly and indirectly, overtly and covertly, in cash and in kind, to Dr. O to induce Dr. O to refer individuals, including Medicaid patients, to pharmacies and Serono Laboratories, Inc. in Massachusetts, for the furnishing of an item, Serostim, and to recommend a prescription to his patients of the drug Serostim, for which payment may be made in whole or in part under a Federal health care program;

All in violation of Title 42, United States Code, Section 1320a-7b(b)(2)(A), and Title 18, United States Code, Section 2.

COUNT TWO: [42 U.S.C. § 1320a-7b(b)(2)(A): Offering to Pay Illegal Remunerations]:

25. The allegations set forth in Paragraphs 1-22 are herein incorporated.
26. On or about March 1-3, 1999 in New York City, New York, defendant

ADAM STUPAK,

did knowingly and willfully offer to pay remuneration, including a kickback and bribe, directly and indirectly, overtly and covertly, in cash and in kind, to Dr. G to induce Dr. G to refer individuals, including Medicaid patients, to pharmacies and Serono Laboratories, Inc. in Massachusetts, for the furnishing of an item, Serostim, and to recommend a prescription to his patients of the drug Serostim, for which payment may be made in whole or in part under a Federal health care program;

All in violation of Title 42, United States Code, Section 1320a-7b(b)(2)(A), and Title 18, United States Code, Section 2.

COUNT THREE: [42 U.S.C. § 1320a-7b(b)(2)(A): Offering to Pay Illegal Remunerations]:

27. The allegations set forth in Paragraphs 1-22 are herein incorporated.
28. On or about March 1-3, 1999 in New York City, New York, defendant

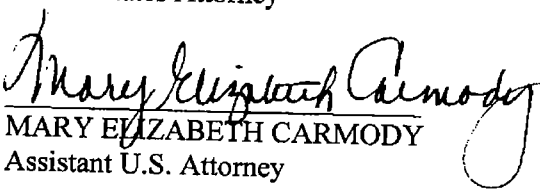
ADAM STUPAK,

did knowingly and willfully offer to pay a remuneration, including a kickback and bribe, directly and indirectly, overtly and covertly, in cash and in kind, to Dr. W to induce Dr. W to refer individuals, including Medicaid patients, to pharmacies and Serono Laboratories, Inc. in Massachusetts, for the furnishing of an item, Serostim, and to recommend a prescription to his patients of the drug Serostim, for which payment may be made in whole or in part under a Federal health care program;

All in violation of Title 42, United States Code, Section 1320a-7b(b)(2)(A), and Title 18, United States Code, Section 2.

MICHAEL J. SULLIVAN
United States Attorney

By:


MARY ELIZABETH CARMODY
Assistant U.S. Attorney

JS 45 (5/97) - (Revised USAO, MA, 1/15/04) Case 1:04-cr-10367-DPW Document 1 Filed 12/15/2004 Page 11 of 12

Criminal Case Cover Sheet

U.S. District Court - District of Massachusetts

Place of Offense: Boston, MA and
Manhattan, NY Category No. II Investigating Agency FBI, FDA, HHS, DO L,
USPS

City _____ Related Case Information:

County _____ Superseding Ind./ Inf. Information Case No. _____
Same Defendant _____ New Defendant _____
Magistrate Judge Case Number _____
Search Warrant Case Number _____
R 20/R 40 from District of _____

Defendant Information:

Defendant Name Adam Stupak Juvenile ☐ Yes ☒ No

Alias Name _____

Address 1334 Club Drive, Hewlit, NYBirth date (Year only): 1964 SSN (last 4 #): 7435 Sex M Race: W Nationality: USADefense Counsel if known: Evan SlavittAddress: Bodoff & Slavitt, LLP

Bar Number: _____

225 Friend Street, Boston, MA

U.S. Attorney Information:

AUSA Mary Elizabeth CarmodyBar Number if applicable 074500Interpreter: ☐ Yes ☒ No

List language and/or dialect: _____

Matter to be SEALED: ☐ Yes ☒ No☐ Warrant Requested☒ Regular Process☐ In Custody

Location Status:

Arrest Date: _____

☐ Already in Federal Custody as _____ in _____☐ Already in State Custody _____☐ Serving Sentence☐ Awaiting Trial☐ On Pretrial Release: Ordered by _____ on _____

Charging Document:

☐ Complaint☒ Information☐ Indictment

Total # of Counts:

☐ Petty☐ Misdemeanor☒ Felony 3

Continue on Page 2 for Entry of U.S.C. Citations

☒ I hereby certify that the case numbers of any prior proceedings before a Magistrate Judge are accurately set forth above.Date: 12/15/04

Signature of AUSA:

Michael Loucks (per)

JS 45 (5/97) - (Revised USAO MA 3/25/03) Page 2 of 2
 Case 1:01-cv-12257-PBS Document 1 Filed 12/15/2004 Page 12 of 12

District Court Case Number (To be filled in by deputy clerk): _____

Name of Defendant Adam Stupak

U.S.C. Citations

	<u>Index Key/Code</u>	<u>Description of Offense Charged</u>	<u>Count Numbers</u>
Set 1	<u>42 U.S.C. § 1320a-7b(b)(2)(A)</u>	<u>kickbacks</u>	<u>1, 2, 3</u>
Set 2	<u>18 U.S.C. § 2</u>	<u>aiding and abetting</u>	<u>1, 2, 3</u>
Set 3	_____	_____	_____
Set 4	_____	_____	_____
Set 5	_____	_____	_____
Set 6	_____	_____	_____
Set 7	_____	_____	_____
Set 8	_____	_____	_____
Set 9	_____	_____	_____
Set 10	_____	_____	_____
Set 11	_____	_____	_____
Set 12	_____	_____	_____
Set 13	_____	_____	_____
Set 14	_____	_____	_____
Set 15	_____	_____	_____

ADDITIONAL INFORMATION: